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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,014

Applicant(s)

NAKAYAMA ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 3-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.
37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-546) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 1-9 are currently pending and present for examination in this application.

Applicants' amendments and arguments filed on 10-14-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically Examiner has withdrawn the rejection of claims directed to non-statutory subject matter under 35 U.S.C. 101 in view of claim amendments. Similarly, Examiner has withdrawn the rejection of claims under 35 U.S.C. 112, 1st paragraph as being non-enabled and lacking written description in view of claim amendments. Examiner has also withdrawn the rejection of claims under 35 U.S.C. 102(b) as being anticipated by Andrianopoulos et al. in view of the claim amendments.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). However, the priority document is in Japanese language. Examiner requests an English translation of the priority document if applicants intend to claim the benefit of the foreign priority date.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 7-9 are directed to transformants further transformed with a polynucleotide encoding a polypeptide with GDP-D-mannose-4,6-dehydratase including variants, mutants and recombinants. Claims 7-9 are rejected under this section of 35 USC 112 because the claims are directed to transformed host cell transformed with a genus of polynucleotides that have not been disclosed in the specification. No description has been provided of the polynucleotide sequences encompassed by the claim. No information, beyond the characterization of the function of the polynucleotide has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of polynucleotides encoding a polypeptide with GDP-D-mannose-4,6-dehydratase including variants, mutants and recombinants within the scope of the claimed genus. The genus of polynucleotides used is a large variable genus including polynucleotides which can have a wide variety of structures. Therefore many structurally unrelated polynucleotides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonin et al. (Plant Physiol., 1997, Vol. 114(3), Sup. page 22, Abstract 20.). This rejection is based upon the public availability of a printed publication. Claims 1-2 of the instant application are drawn to a protein with SEQ ID NO:1 having a GDP-4-keto-6-deoxy-D-mannose-3, 5-epimerase-4-reductase activity and a polynucleotide encoding the same. Bonin et al. disclose a polypeptide designated as *GER1* having GDP-4-keto-6-deoxy-D-mannose-3, 5-epimerase-4-reductase activity and a cDNA isolated from *A.thaliana* and encoding the above polypeptide. While the above reference does not disclose the actual amino acid sequence or the polynucleotide sequence, as the source of the reference cDNA and the enzyme are the same as that of the claimed DNA and polypeptide Examiner also takes the position, that characteristics such as amino acid/nucleotide sequences are inherent characteristics. See the evidentiary reference (SPTREMBL database accession No. O49213, June 1998), enclosed herewith. Thus Bonin et al. anticipate claims 1-2 of this application as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

In response to the previous Office action, applicants have traversed the above rejection arguing that the published amino acid sequence of the above reference and that of the claimed protein are not 100% identical and that it is only 93.7% identical and therefore the claimed protein does not inherently possess the same amino acid sequence as that of the reference and therefore is not anticipated. Examiner respectfully disagrees. This is because the evidentiary sequence alignments (with that of Bonin et al. from SPTREMBL database accession no. O49213, June 1998 enclosed herewith) that the Examiner has matches 100% with the claimed amino acid sequence. Therefore, contrary to applicant's argument the reference of Bonin et al. does anticipate claims 1-2 as written.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (J. Biol. Chem., 1988, Vol. 263(4):1693-97). This rejection is based upon the public availability of a printed publication. Claim 1 of the instant application are drawn to a protein with SEQ ID NO:1 having a GDP-4-keto-6-deoxy-D-mannose-3, 5-epimerase-4-reductase activity. Chang et al. disclose a polypeptide designated having GDP-4-keto-6-deoxy-D-mannose-3, 5-epimerase-4-reductase activity. While the above reference does not disclose the actual amino acid sequence,

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in view of the reference enzyme and the claimed enzyme having the identical function, Examiner takes the position, that characteristics such as amino acid/nucleotide sequences are inherent characteristics and therefore the reference enzyme inherently has the same amino acid sequence as that claimed in the instant application. Thus Chang et al. anticipate claim 1 of this application as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. as applied to claim 1 above, and further in view of the common knowledge in the art to deduce the polynucleotide sequence based on the genetic code. Claim 2 is drawn to a polynucleotide encoding the polypeptide with GDP-4-keto-6-deoxy-D-mannose-3, 5-epimerase-4-reductase

activity. Chang et al. teach the above polypeptide sequence. However, the reference does not teach the polynucleotide sequence encoding the said polypeptide.

Using the polypeptide of Chang et al. it would have been obvious to those skilled in the art to use the commonly known methods of amino acid sequencing and derive the amino acid sequence of the said polypeptide. Using such polypeptide sequence it would have been obvious to those skilled in the art to arrive at the polynucleotide sequence encoding said polypeptide based on the standard genetic code tables that are also commonly known in the art. One of ordinary skill in the art would have been motivated to do so in order to make recombinant protein using the polynucleotide. One of ordinary skill in the art would have a reasonable expectation of success since many other polynucleotide sequences have been derived from known amino acid sequence information and the genetic code information. Therefore Chang et al. render the above invention *prima facie* obvious to those skilled in the art.

Conclusion

Claims 3-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura

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Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao
Primary Examiner, Art Unit 1652,
December 30, 2003